Family Planning Advocates of NYS
17 Elk Street
Albany, New York 12207-1002
Phone: (518) 436-8408
Fax: (518) 436-0004
Website: www.fpaofnys.org

October 7, 2005

Food and Drug Administration, HHS
Division of Dockets Management
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: RIN 0910-AF72
Docket No. 2005N-0345

Dear Acting Commissioner von Eschenbach:

Family Planning Advocates (FPA) is a nonprofit organization that represents family planning providers in New York State, including the state's thirteen Planned Parenthood affiliates. As an organization, we are committed to the goal of reducing the rate of unintended pregnancy in New York State. Increasing access to emergency contraception (EC) is important to achieving that goal, and we therefore support making Plan B an over the counter medication for women of all ages.

In response to the questions posed in RIN 0910-AF72, FPA believes the first three questions (1A, 1B and 1C) should be answered in the negative, making it unnecessary to address the remaining questions. We do not believe there is any confusion over the interpretation of section 503 of the Federal Food, Drug, and Cosmetic Act. We feel it is clear that the delays in approving the application to classify Plan B as an over the counter medication, and request for information these comments address, are the result of inappropriate political interference as opposed to "significant confusion" over section 503's interpretation. The questions over how to label, market and enforce an age-restricted medication are the end result of a process that has allowed politics and ideology to interfere with decisions that should be based on medical fact and reason.

2005N-0345

C61

The mission of the FDA is to protect "the public health by assuring the safety, efficacy, and security of human and veterinary drugs...," not to pander to politically motivated opposition where objections have no grounding in medical or scientific research. Because the questions posed in the Request for Information are not the result of medically supportable facts that necessitate placing age restrictions on the medication's use, it is simply inappropriate for the questions to be considered in conjunction with the FDA's consideration of the Plan B application. We do not support initiating a rule-making process in relation to Plan B.

EC approval process diverges from FDA mission

We are concerned that the FDA has diverged from its role of determining whether a medication that is the subject of an application seeking exemption from prescription-dispensing requirements, is "safe and effective for use in self-medication . . . ,"[1] FPA has watched with dismay as politics has interfered with the application to make Plan B available as an over the counter medication. Despite the recommendation of two FDA advisory committees that the application be approved, the application was denied. Similarly, the pending application has now been deferred for reasons that have no grounding in science.

It is not the role of the FDA to limit access to a medication because some factions of society are morally opposed to its use. If limiting access to a medication, which has been shown to be safe and effective, is not necessary to protect public health, then it should be exempted from prescription-dispensing requirements.[2] The FDA exists to protect public health by making evidence-based decisions on drug safety; the agency should not allow political agendas to substitute for science in making health decisions.

Evidence shows EC is suitable for OTC use

The FDA has received substantial documentation that offers clear and convincing evidence that EC is a safe and effective drug suitable for self-medication.

Overwhelming evidence shows that EC is a safe and effective medication whose benefits are best realized by removing unnecessary barriers to access. This evidence has caused the American Medical Association and the American College of Obstetricians and Gynecologists to support making EC an over the counter medication. This support would not have been forthcoming if there were valid evidence showing it would be inadvisable or dangerous to public health if EC could be obtained without a doctor's prescription.

EC benefits

Unintended pregnancy is a public health issue that has long-ranging health impacts. Women with unintended pregnancy forego the opportunity to receive pre-conception counseling to improve the health of the fetus and are more likely to have low birth weight babies and experience a higher rate of neonatal mortality.[3]

---

[1] 21 C.F.R. §310.200(b).
[2] *See* 21 C.F.R. §310.200(b).
[3] R. Bonoan and J. Gonen, "Promoting Healthy Pregnancies: Counseling and Contraception as the First Step," Washington Business Group on Health, August 2000.

Increasing access to emergency contraception would play a significant role in reducing the incidence of unintended pregnancy—a goal that would not only serve to improve the health of women and children, but would also save money for state, federal and private insurance plans who must bear the costs of health problems related to unintended pregnancy. A study published by New York State Comptroller Alan Hevesi found that increasing access to EC, including making it available over the counter, would result in 122,000 fewer unintended pregnancies and 82,000 fewer abortions every year in New York.[4] The study projected that Medicaid costs would be cut by $254 million a year, and private insurers would save nearly $200 million.

Making EC available over the counter would enable women to obtain the medication in a timely manner. EC is a time-sensitive medication that is most effective the sooner it is taken after unprotected intercourse. Making the medication available over the counter will enhance women's ability to prevent unintended pregnancy by allowing them to obtain the medication when it has the greatest potential for effectiveness.

Use of EC by teens

Although concern about the use of EC by teens has been stated as the reason for denying the original application and then delaying a final decision on the application to make Plan B available to women aged 16[5] and over, widespread support among mainstream medical organizations for making emergency contraception available over the counter makes that assertion untenable. Claims by EC opponents that easier access to EC will cause teens to engage in increased or unprotected sexual activity are not supported by evidence-based studies.

Medical research shows that enhanced access to emergency contraception does not lead to increased rates of unprotected intercourse or pose a risk to minors. A study published in the January 5, 2005 edition of *JAMA* found that women with enhanced access to EC are no more likely to engage in unprotected sex or abandon use of other contraception methods than women who do not have easy access to the pills.[6] The article's findings are based on a study of over 2000 sexually active women aged 15-24. A similar study also found that increased access to emergency contraception did not cause minors to engage in unprotected intercourse.[7]

In addition, the American Academy of Pediatrics (AAP) is supportive of increasing the availability of emergency contraception, including over the counter access for teens.[8] In its position paper on emergency contraception, AAP states, "An increase in awareness and availability of emergency contraception to teens does not change reported rates of sexual activity

---

[4] New York State Office of the State Comptroller, "Emergency Contraception in New York State: Fewer Unintended Pregnancies and Lower Health Care Costs," November 2003.

[5] We note that the most recent decision to defer a final decision on Barr Labs' application contained a reference to making the medication available to women aged 17 and over, however, the application was for women aged 16 and over.

[6] Raine TR et al. (2005) Direct Access to Emergency Contraception Through Pharmacies and Effect on Unintended Pregnancy and STIs. *Journal of the American Medical Association,* 293(1):54-62.

[7] *See,* Gold MA, Wolford JE, Smith KA, Parker AM. The effects of advance provision of emergency contraception on adolescent women's sexual and contraceptive behaviors. *J Pediatr Adolesc Gynecol.* 2004;17:87-96.

[8] *See,* American Academy of Pediatrics Policy Statement on Emergency Contraception, *Pediatrics* 2005;116:1038-1047.

or increase the frequency of unprotected intercourse among adolescents."[9] This medical support should dispel any myths that the medication is somehow dangerous to a minor's health.

Conclusion

Because there is no scientific basis for restricting access to teens, it would be inappropriate to consider the questions posed in the Request for Information in conjunction with the application to approve Plan B as an over the counter medication. In the interest of women's health and the application of scientific data, we strongly believe the pending application to allow Plan B to be sold over the counter should be approved without any age restrictions.

Sincerely,

JoAnn M. Smith
President and CEO
Family Planning Advocates of New York State

[9] American Academy of Pediatrics Policy Statement on Emergency Contraception, *Pediatrics* 2005;116:1038-1047.